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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/611,442	06/30/2003	C: Richard Hutchinson	020547-002510US	4956

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TOWNSEND AND TOWNSEND AND CREW, LLP  
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EXAMINER
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ROBINSON, HOPE A

ART UNIT	PAPER NUMBER
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1652

MAIL DATE	DELIVERY MODE
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02/21/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/611,442	Applicant(s) HUTCHINSON ET AL.	
	Examiner Hope A. Robinson	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 October 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3, 16, 17, 21, 22 and 24-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 16, 17, 21, 22, 24, 25 and 28-31 is/are rejected.
- 7) ☒ Claim(s) 26, 27 and 32 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **SUPPLEMENTAL DETAILED ACTION**

### ***Application Status***

1. This is a Supplemental Office Action to remove Finality of the previous Office Action mailed.
2. Applicant's response to the Office Action mailed August 1, 2007 on October 23, 2007 is acknowledged.

### ***Claim Disposition***

3. Claims 1-3, 16-17, 21-22 and 24-32 are pending and are under examination.
4. The following rejection is or remains applicable.

### ***New-Claim Objection***

5. Claims 25-28 and 32 are objected to because of the following informalities:

Claim 25 is objected to because of the following typographical error "...SEQ ID NO:1)", see line 11 of the claim.

Claims 26-27 and 32 are objected to as depending from a rejected based claim.

Claim 28 is objected to because it a comma (,) is missing between "...SEQ ID NO:1 and MegBIII...", see line 8 of the claim.

Correction of the above is required.

***New-Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

6. Claim 29 is rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter, which applicant (s) regard as their invention.

Claim 29 is confusing because the claim depends from claim 25 which recites that the nucleic acid "optionally" encodes the MegBVI enzyme, which means that the encoding of the "MegBVI enzyme" is elective or possible. Thus, the encoding of the MegBVI enzyme does not appear to be certain and claim 29 is directed to "the nucleic acid that encodes the MegBVI enzyme". However note that claim 28 is directed to the nucleic acid encoding the MegBVI enzyme.

***Amended-Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1-3, 16-17, 21-22, 24-25 and 28-31 are rejected under 35 U.S.C. 102(e) as being anticipated by McDaniel et al. U.S. Patent No. 6,524,841, October 8, 1999).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

McDaniel et al. teach recombinant nucleic acids that encode all or a portion of the megAI gene of the megalomicin polyketide synthase of *Micromonosporas megalomicea* (abstract). McDaniel et al. disclose modifying enzymes which include those enzymes involved in the conversion of 6-DEB into a megalomicin, said enzymes are encoded by megF, megK among others (paragraph [45]), see claims 1-3. Claim 28 is anticipated based on the teaching of MegBVI in Table 1 of the patent (see column 15). Mc Daniel et al. also teach a host cell (paragraph [16]), vector (paragraph [14]) and method of making said protein (paragraph [12]), see claims 16-17 and 21-22. Note that the patent discloses a drawing (see page 1 of the patent and Fig. 9) that displays a cosmid (KOS079) having 40kb which is identical to the one shown in Figure 1 of the claimed invention. Thus, the genes for example, MegK or MegBVI, would be on

this segment. The gene cluster claimed is from the same organism and cosmid as claimed. In addition, the patent displays the cosmid (KOS079-124B, having 40kb) which would have the genes for example MegF, MegBIII, or MegL on that segment (see claim 24). As the same cosmids from the same organism genome is disclosed in the patent, the genes would inherently be present, thus claims 25 and 28 are anticipated. Therefore, the limitations of the claims are met by the reference.

8. Claims 1-3, 16-17, 21-22, 24-25 and 28-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Volchegursky et al. (Molecular Microbiology, vol. 37 (4), pages 752-762 , 2000) as evidenced by McDaniel et al. U.S. Patent No. 6,524,841, October 8, 1999).

Volchegursky et al. teach the cloning and sequencing of a 48kb segment of the megalomicin (meg) biosynthetic gene cluster which contains the modular polyketide synthase (PKS) and the complete pathway for megosamine biosynthesis. Volchegursky et al. disclose enzymes such as megF (see claims 1-3, page 752 and 755 of the reference). The process used by Volchegursky et al. involves host cells, vector and said process produced the enzymes as claimed, therefore, claims 16-17 and 21-22 are anticipated (see pages 759-760). Note that the reference provides a drawing on page 754 which shows two cosmids (KOS079-138B and KOS079-124B) which would inherently possess the genes recited in for example claim 1 as evidenced by the McDaniel et al. patent (see abstract and Figure 9). As the same cosmids from the same organism genome is disclosed in the patent, the genes would inherently be present, thus

instant claims 24-25 and 28 are anticipated. Therefore, the limitations of the claims are met by the reference.

***Response to Applicant's Arguments:***

9. Applicant's arguments have been fully considered and the rejections/objections of record have been withdrawn. Note however, that the art rejection remains for the reasons stated above and herein. The references remain relevant because the references teach the same cosmids from the same organism genome, thus would inherently possess the recited genes whether sequenced or not, hence the reason for the inclusion of claims 25 and 28 into the rejection. Both the Volchegursky et al. and the McDaniel et al. references disclose KOS079-138B exhibited in Figure 1 of the instant application which comprises for example gene MegK and disclose another cosmid KOS079-124B which would possess genes such as MegL as evidenced by the length demonstrated in the patent (see page 1 of the McDaniel et al. patent). Therefore, the references remain relevant to the claimed invention. It is noted that applicant state that neither the genes recited in claim 1 nor their nucleotide sequences are disclosed in the reference (see page 6 of the response). This argument is not persuasive since the sequence is simply another characteristic, thus, the rejection remains. Furthermore, the recitation of the open language "comprising" supports the presence of the gene whether sequenced or not. It is suggested that closed language is used such as "consists" in association with the specific fragments. Applicant is reminded that

any amendments made to the application must find support in the instant specification. Note that a new rejection has been instituted under 35 USC 112, second paragraph for the reasons stated above.

***Conclusion***

10. No claims are presently allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope A. Robinson whose telephone number is 571-272-0957.

The examiner can normally be reached on Monday-Friday.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy, can be reached at (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Application/Control Number:  
10/611,442  
Art Unit: 1652

Page 8

Hope Robinson, MS 

Primary Examiner

HOPE ROBINSON  
PRIMARY EXAMINER